seconds after being placed into the mouth and being capable of rapidly exposing said spacing layer when in the stomach of a patient; and

at least one pharmaceutically acceptable excipient provided in an amount of between greater than zero and less than 100%, based on the weight of the finished dosage form.

REMARKS

An amendment in response to the March 2, 2001 Final Office Action was originally due on June 2, 2001. Applicants hereby request for one-month extension of time from June 2, 2001 to July 2, 2001.

Claims 1, 4 to 18, and 21 were pending. Claims 1, and 14 are amended. Upon entry of this Amendment, claims 1, 4 to 18, and 21 will be under examination.

The amendments to the claims 1, and 14 are fully supported by the original specification and do not raise any issue of new matter. Support for the amendments to claims 1 and 14 can be found, *inter alia*, in lines 21-24, page 11 of the specification. Applicants believe that the amendments to the claims 1, and 14 address the rejections and place the present application in condition for allowance. These amendments also place the present application in better form for consideration on appeal. Accordingly, entry of this Amendment is respectfully requested.

REJECTION UNDER 35 U.S.C §102(b)

Claims 1, 4, 5, 14, and 21 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Kais et al., U.S. Patent No. 5,516,524 ("Kais"). Applicants disagree. However, in order to expedite the prosecution of this application, applicants have amended claims 1 and 14 to clarify that the spacing layer of the taste masked formulation comprises ethyl cellulose, methyl

cellulose, hydroxypropyl cellulose, hydroxy propyl methyl cellulose, polyalkylene glycols, polyalkylene oxides, sugars, sugar alcohols, shellacs, acrylics, or mixtures thereof.

Under M.P.E.P. § 2131, to anticipate a claim, the reference must disclose every element of the claim. In this case, Kais does not disclose each and every element of the claims, as amended, because Kais does not disclose the use of ethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxy propyl methyl cellulose, polyalkylene glycols, polyalkylene oxides, sugars, sugar alcohols, shellacs, acrylics, or mixtures thereof as an internal spacing layer of the claimed taste masked formulation. Nor does Kais disclose the use of a material which is generally insoluble in saliva at a neutral to basic pH and completely soluble in saliva at a pH of less than about 6.5 as the outer layer.

Therefore, under the M.P.E.P. § 2131 standard, Kais does not anticipate claims 1, 4, 5, 14, and 21, as amended. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

REJECTIONS UNDER 35 U.S.C §103(a)

Claims 1, 4 to 18 and 21 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kais as applied to claims 1, 4, 5, 14, and 21. Applicants respectfully traverse this rejection as Kais does not teach or suggest the subject matter of claims 1, 4 to 18 and 21, as amended. Kais constitutes a teaching away from the present invention as Kais discloses, in column 5, lines 44-49, that the pH sensitive polymers used, as well as gum coatings used, preferably dissolve under basic environments of the small intestines. As a result, the coatings of the formulation in Kais would dissolve quickly in a patient's mouth if the pH sensitive material in Kais is used as the outer layer. To the contrary, the present invention uses a material which is generally insoluble in saliva at a neutral to basic pH and completely soluble in saliva at a pH of less than about 6.5 as the outer layer, and uses ethyl cellulose, methyl cellulose, hydroxypropyl cellulose,

hydroxy propyl methyl cellulose; polyalkylene glycols, polyalkylene oxides, sugars, sugar alcohols, shellacs, acrylics, or mixtures thereof as the spacing layer.

Therefore, from the teachings of Kais, it would not be obvious to a skilled artisan to make the claimed formulations. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

If any additional fee is required, the examiner is also authorized to charge any such fee to our Deposit Account No. 12-1095.

CONCLUSION

In view of the amendments and the remarks, the present application is in condition for allowance. Entry of this Amendment, and further and favorable action in the form of a Notice of Allowance with respect to claims 1, 4 to 18 and 21 are respectfully requested.

Respectfully submitted,
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